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Impact of Periprocedural Transesophageal Echocardiography on Mortality in Patients Undergoing Transcatheter Aortic Valve Implantation: Analysis from the Brazilian Registry

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Background: The aim of this study is to assess the utility of transesophageal echocardiography (TEE)-guided procedure on clinical outcomes in pts with severe aortic stenosis undergoing transcatheter aortic valve implantation (TAVI).

Methods: Between January 2008 and February 2012, 418 pts with symptomatic severe aortic stenosis underwent TAVI at 18 sites and were enrolled in the Brazilian multicenter registry. We assessed outcomes of pts who underwent TAVI using periprocedural TEE (TEE; n= 295) vs. with no TEE-guided procedure (noTEE; n=123). Stepwise Cox multivariable regression analysis was performed to assess the association between the TTE-guided procedure and long-term mortality.

Results: Pts treated with TEE vs. noTEE tended to be younger (81.20±8.87 vs. 82.24±7.33 years, p=0.21), with higher rates of diabetes, hyperlipidemia, hypertension, history of angina, and more likely to receive Sapien than CoreValve (18.6% vs. 2.4%; 81.4% vs. 97.6%; p<0.001, respectively). Compared with pts with noTEE, those with TEE had lower STS risk score (13.32±11.48% vs. 16.16±11.40%; p=0.02), but similar EUROScore (19.70±21±43% vs. 21.43±15.55%; p=0.24). TEE-guided procedure was associated with a significant reduction in 5-year all-cause mortality (19.0% vs. 37.4%; p<0.001). By multivariable analysis, TEE (vs. noTEE) was an independent predictor of freedom from death (HR 0.63; 95% CI [0.42 to 0.93]; p=0.02).

Conclusions: In pts with severe aortic stenosis, TAVI guided by TEE was associated with lower long-term mortality as compared to pts without TEE-guided procedure. A randomized trial is required to determine the advantage of this approach.

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Improvement in Aortic Valve Area Using a New “Hour Glass” Shaped Valvuloplasty Balloon Compared with Standard Cylindrical Balloons in Severe Aortic Stenosis Patients

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Background: Balloon (bal) aortic valvuloplasty (BAV) has reemerged with transcatheter valve therapy. Cylindrical bal have been the device of choice despite limitations. The V8 (InterValve Inc.) bal with larger segments separated by a narrowed waist is designed to permit enhanced fixation and better leaflet opening without annular compromise.

Methods: We report our experience using the V8 bal in 20 matched patients (pts) receiving BAV compared to a subset of 20 pts from a 403 pt BAV database which used cylindrical bals. Pts were propensity matched on a 1:1 basis on age, gender, left ventricular ejection fraction (LVEF), and baseline aortic valve area (AVA). Endpoints included change in AVA by echo, change in aortic insufficiency (AI), and new atrioventricular conduction defect's (AVCD) by 24-hour ECG. The need for post-procedure temporary pacemaker (TPM) or new permanent pacemaker (PPM) was noted. Maximum bal diameter (dia) for each patient was recorded. Reported V8 dia were of the larger aortic root segments of the bal hour glass bal. Major adverse events (MAE) included procedure related death, emergency surgery or stroke.

Results: V8 and cylindrical bal groups were similar across age, sex, Society of Thoracic Surgeons' risk score, LVEF, and baseline AVA. The change in AVA from baseline to post-procedure trended towards being larger for V8 pts than cylindrical bal pts (0.30cm² ± 0.23 vs. 0.17 ± 0.21; p=0.063) and max bal size was significantly larger for V8 pts enabled by the bal shape. There were no differences in outcomes of TPM, PPM, AVCD, or MAE (Table 1).

	V8 Balloon (n=20)	MHI Cohort (n=20)	P-Value
Age (Years), Mean(SD)	83.1 ± 7.5	85.5 ± 6.8	0.31
Male, (%)	13 (65.0)	14 (70.0)	0.74
STS Score (%), Mean(SD)	9.8 ± 7.0	11.5 ± 9.8	0.64
LVEF (%), Mean(SD)	44.9 ± 18.3	41.9 ± 19.5	0.62
Maximum Balloon Diameter (mm), Mean(SD)	26.1 ± 1.5	24.2 ± 1.1	<0.001
Baseline AVA (cm ²), Mean(SD)	0.77 ± 0.22	0.78 ± 0.22	0.95
Post AVA (cm ²), Mean(SD)	1.07 ± 0.34	0.94 ± 0.24	0.17
Change AVA (cm ²), Mean(SD)	0.30 ± 0.23	0.17 ± 0.21	0.063
Change in AI (Class improvement)			
3 class deterioration, (%)	0 (0)	1 (6.3)	0.45
2 class deterioration, (%)	0 (0)	0 (0)	
1 class deterioration, (%)	6 (30.0)	3 (18.8)	
No change, (%)	13 (65.0)	9 (56.3)	
1 class improvement, (%)	1 (5.0)	2 (12.5)	
2 class improvement, (%)	0 (0)	1 (6.3)	
New AVCD*, (%)	0 (0)	0 (0)	—
Temporary Pacemaker*, (%)	1 (5.0)	1 (5.0)	1.00
New PPM*, (%)	0 (0)	0 (0)	—
MAE*, (%)	0 (0)	1 (5.0)	1.00

Abbreviations: STS = Society of Thoracic Surgeons; LVEF = left ventricular ejection fraction; AVA = aortic valve area; AI = aortic insufficiency; AVCD = atrioventricular conduction disorder; PPM = permanent pacemaker; MAE = major adverse event (defined as mortality, emergency surgery, or stroke).
* Fisher's exact test used to assess statistical significance.

Conclusions: Preliminary findings in this small experience suggest an advantage for enhancing AVA when using the V8 bal compared to cylindrical bals. Additionally, there was no evidence of increased AI class or occurrence of AVCD or MAE. Findings from a multicenter registry will be available for presentation.

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Treatment and Clinical Outcomes of Transcatheter Heart Valve Thrombosis: Multi-center Registry

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Background: Valve thrombosis after surgical bioprosthetic aortic valve replacement is uncommon. This has yet to be evaluated in the context of transcatheter aortic valve implantation (TAVI).

Methods: Between January 2008 and February 2013, all consecutive patients who underwent TAVI were analyzed in this multi-center registry (9 centers). Transcatheter heart valve (THV) dysfunction was defined as aortic valve area <1.2 cm² and mean aortic valve gradient ≥20 mmHg or peak velocity ≥3 m/s, or moderate or severe prosthetic valve regurgitation. THV thrombosis was defined as THV dysfunction secondary to thrombosis, which was diagnosed based on the timing post-TAVI, response to anticoagulation therapy, echo findings or histopathology.

Results: Probable valve thrombosis was observed in 15 patients at median follow-up period of 6 months (IQR 4 to 10) after TAVI. Mean age was 80.1 years and 9 were male gender. In majority of cases (n=12, 80%), the Edwards THV was implanted. The most common clinical presentation was dyspnea on exertion (n=8) whereas 3 patients were asymptomatic. One patient presented with acute heart failure and a non-ST elevation myocardial infarction. Transvalvular gradient was found to be markedly elevated in all patients who presented with exertional dyspnea. Thickened leaflets without visible thrombus were observed in 4 (23%) patients, thrombotic apposition of leaflets or thrombotic mass on leaflets in the remaining 11 (77%) patients. In 8 (53%) patients, anticoagulation resulted in normalization of transaortic gradient within 3 months. In 4 (27%) patients, anticoagulation was initiated and follow-up is anticipated. Two (13%) patients underwent successful surgical aortic valve replacement, while the remaining 1 (7%) died during the index hospitalization.

Conclusions: Although a rare phenomenon, THV thrombosis may occur within the first 2 years following TAVI and usually presents with dyspnea and an increased gradient. It would appear that anticoagulation is very effective in normalizing the gradient and should be considered even in patients without visible thrombus on echo. These data suggest that further studies are required to evaluate the importance of DAPT versus anticoagulation after TAVI.